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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/361,542	07/27/99	DOBROZSI	D 7247M

EXAMINER	
PULLIAM, A	
ART UNIT	PAPER NUMBER
1615	13

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THE PROCTER & GAMBLE COMPANY
PATENT DIVISION
HEALTH CARE RESEARCH CENTER
8340 MASON-MONTGOMERY ROAD
MASON OH 45040

DATE MAILED: 09/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/361,542	DOBROZSI, DOUGLAS JOSEPH	
	Examiner	Art Unit	
	Amy E Pulliam	1615	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 March 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,24,26 and 28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,24,26 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt is acknowledged of the Request for a CPA, and the Preliminary Amendment C, both received March 13, 2001.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-12, 24, 26, and 28 remain rejected under 35 U.S.C. 103(a) as being unpatentable over EP 733 357 to Boltri *et al.* (hereinafter Boltri). Boltri discloses a topical formulation which is nebulizable by a mechanical pump, and contains colloidal silica (abstract). Boltri further teaches that the pharmaceutical formulation of his invention comprises colloidal silica in an amount from 2 to 15%, and a pharmaceutically active ingredient, as well as water and any other excipients conventionally used in pharmaceutical techniques (p 2, l 22-26). Further, Boltri teaches that the average diameter of the silica particles is between 7 and 40 nm, which reads on applicant's claim to less than 1 micron. Boltri also teaches that the composition can be used for topical, vaginal, nasal, and otological administration (p 3, l 15-17).

This disclosure teaches the above claims, because these claims are drawn to a composition, and Boltri teaches the same components in the composition. Further, because Boltri teaches the same components in the composition, the ratios and viscosities claimed by applicant are considered inherent to the composition, and absent any evidence to the contrary, these characteristics render no patentable weight to the instant application.

Boltri does not teach the specific inclusion of citric acid, however Boltri does teach the inclusion of pharmaceutical excipients in general, and it is the position of the examiner that one of ordinary skill in the art would use any well known excipient in the formulation disclosed by Boltri.

Further, Boltri does not disclose the method of coating the alimentary canal or treating the upper respiratory tract. However, based on the teachings that the formulation can be nebulized, it is the position of the examiner that one of ordinary skill in the art would take this to mean the composition could be inhaled through means well known in the pharmaceutical art. Therefore, one of ordinary skill in the art would have been motivated to use Boltri's formulation to treat the alimentary canal through inhalation therapy. One of ordinary skill in the art would expect the same results in this type of treatment as in treating the nasal and vaginal areas. Therefore, this invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's arguments have been fully considered but are not found persuasive. Applicant argues that the reference does not disclose oral administration. This argument is not persuasive for several reasons. First, claims 1-12 are drawn to compositions, and future intended use does not bear patentable weight to a composition claim. Second, the reference teaches administration to areas containing mucosal tissue, specifically nasal, vaginal and otological administration. It is well known in the pharmaceutical art that the gastrointestinal tract and the inside of the mouth are both lined with mucosal tissue. It is the position of the examiner that one of ordinary skill in the art would be motivated to use a composition, which is shown to have success on mucosal tissue, on any mucosal surface, depending on the specific active ingredient employed and the specific treatment desired. Third, according to applicant's own definition, found at page 1, lines 17-20 of the specification, "bioadhesion implies that at least one of the surfaces is of biological origin. When the surface is the adherent mucus layer covering one of the epithelial, such as the inside of the gastrointestinal tract, nasal tract, or vaginal cavity, the term mucoadhesion is used." Therefore, applicant admits that there is a relationship between the different mucosal layers found within the body, and that a bioadhesive composition would be effective on any of these layers. Lastly, one could argue that topical administration encompasses administration to the topical surface on the inside of the mouth. In many instances, topical is intended to be interpreted this broadly, and because the reference teaches topical administration to mucosal, it reads on applicant's claimed limitation.

Applicant further argues that Boltri teaches a high viscosity, nearly semi-solid composition, which requires nebulization prior to administration. Applicant further states that a thixotropic composition would produce unacceptable aesthetics for use as a non-nebulized swallowable composition because without the nebulization the composition would remain too thick for administration through swallowing. The examiner recognizes that Boltri does discuss nebulization of the product. However, the examiner also points out that the reference teaches a wide range concerning the amount of water and colloidal silica present. Boltri teaches that water may be present in amounts ranging from 60-97%, and the colloidal silica may be present in an amount as small as 2% (p 2, l 33-38). By Boltri's teaching of such high amounts of water, the reference implicitly teaches flowable, liquid compositions, although it is not directly stated. More specifically, the thickness, and flowability of the composition will depend on the amount of water, and of colloidal silica present, and as the reference discloses wide ranges for these two components, it also teaches a range of flowability. For these reasons, the above rejection is maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is (703) 308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

AEP
September 19, 2001

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600